

Falsified medicines taint global supply

April 20 2015

When you take a medication for, say, high cholesterol, do you know that pill is really what the label says it is? Depending upon the type of medicine and where you live, the threat of falsified medications (also referred to as counterfeit, fraudulent, and substandard) can be quite real, yet the full scope and prevalence of the problem is poorly understood, say researchers at University of California, San Diego School of Medicine in a new report published April 20 in the *American Journal of Tropical Medicine and Hygiene*.

Counterfeit medicines have traditionally been defined as those for which the identity or source is mislabeled in a way that makes them appear to be a genuine product when they are not, though definitions of the problem itself are the subject of international debate.

The UC San Diego report is part of a special journal supplement featuring a variety of studies examining aspects of the "global pandemic of falsified medicines." Produced by diverse universities and institutions across the country and world, the supplement investigates the quality of vital, broadly sold drugs, such as anti-malarials and antibiotics; new tests and assays to detect [counterfeit drugs](#); and proposed policy changes and laws to reduce the distribution and sale of falsified medications.

The UC San Diego study looked at the depth of counterfeit drug penetration in global legitimate medicine supply chains. "Our study was based on data from the Pharmaceutical Security Institute (PSI), a non-profit organization with members from the pharmaceutical security community," said lead author Tim K. Mackey, MAS, PhD, assistant

professor of anesthesiology and global public health, director of the Global Health Policy Institute and associate director of the joint masters program in health policy and law. "PSI data is collected from its industry members, law enforcement, drug regulators, the pharmaceutical industry, and media reports, and confirmed by a team of multilingual investigators. It's the only study of its kind with global statistics on counterfeit medications. We limited the scope to legitimate supply chains, places where you expect to get legitimate medicines, such as hospitals and pharmacies."

The primary finding and "surprise," said Mackey, is how little is known about the precise scope of the problem and how few mechanisms exist to monitor it despite the availability of some data. During the period studied, 2009 through 2011, there were 1,510 total counterfeit incidence reports tabulated by the PSI. But "nobody has a good idea how big the problem really is," said Mackey. "There are guesses, but it's hard to get accurate statistics on a criminal activity of this magnitude."

The falsified drug problem is not new, just bigger than ever, say experts. It covers widely used drugs, notably anti-malarials, and more high-value, high-demand drugs, such as medications to treat HIV/AIDS, serious cardiovascular disease and cancer. According to a 2000 World Health Organization report, almost one-third of identified counterfeit drugs contained no active ingredient; and more than 20 percent either had incorrect quantities of active ingredients or contained the wrong ingredients. Other fraudulent practices included false packaging and high levels of impurities.

Each year, it's estimated between 100,000 and 1 million people die from using counterfeit drugs.

"The most important takeaway of our study is that we don't have the necessary data or surveillance to effectuate meaningful public health

interventions or policy change," Mackey said. "As an example, more than half of our dataset was from four countries, not necessarily because these countries have the most counterfeits, but possibly because they are countries of transit or are the ones actively looking for them." The researchers also noted that scores of countries filed no counterfeit incidence reports during the study period.

"We hope this study will prompt key opinion leaders and policymakers to make necessary changes to surveillance, security and improvements to pharmaceutical governance of drug supply chains in order to prevent future falsified medicine incidents and protect patients worldwide," said Mackey.

Provided by University of California - San Diego

Citation: Falsified medicines taint global supply (2015, April 20) retrieved 20 June 2024 from <https://medicalxpress.com/news/2015-04-falsified-medicines-taint-global.html>

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